

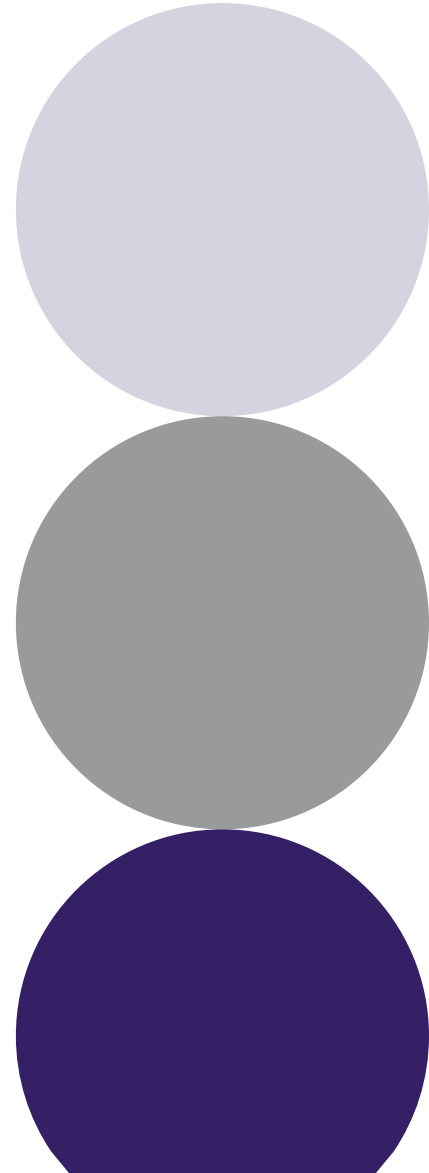


AMERICAN ACADEMY
OF OPHTHALMOLOGY®

Protecting Sight. Empowering Lives.®

AAO Presentation on Access to Compounded Drugs for Office-Use

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American Academy of Ophthalmology





Overview

- Access to compounded and repackaged drugs is vital to ensuring ophthalmologists can provide quality and effective care to our patients.
- The Academy has concerns regarding the ability of outsourcing facilities to meet ALL ophthalmology needs for compounded drugs for office-use.
- Small-batch compounded antivirals and antibiotics remain unavailable through 503B outsourcing facilities.



Importance of Office-Use Access

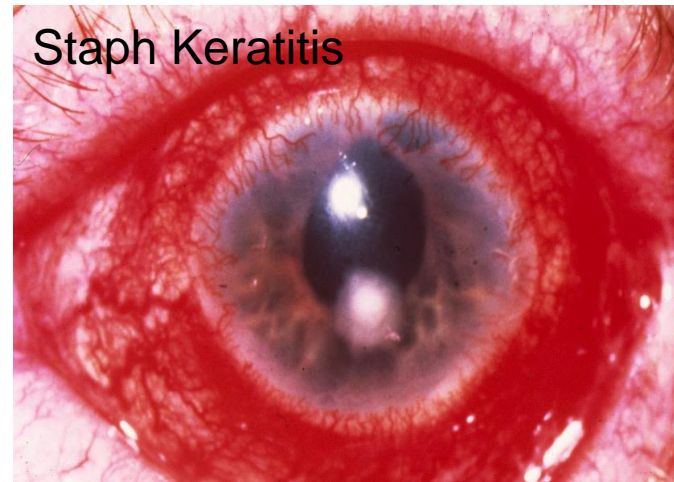


- Ophthalmologists rely on access to compounded drugs for office-use to treat our patients.
- Immediate access is critical when patients come into office with urgent care needs, such as emergent infections of the eye
- Delay in treatment, even by a few hours, can result in permanent vision loss for a patient
- In other cases, such as the treatment of AMD, ophthalmologists need to have drugs on hand because they will not know if a patient needs treatment until an examination is performed



Specific Drugs Unavailable

- Antibiotics for bacterial keratitis, endophthalmitis
 - Cefazolin
 - Gentamycin
 - Tobramycin
- Antimicrobial for acanthamoeba keratitis: PHMB
- Antiviral for viral keratitis, retinitis: Ganciclovir





Access Barriers

- The Academy has been told by 503B facilities that produce ophthalmology products that financial considerations are a key barrier to availability of compounded drugs ordered in low-volume
- Based on our outreach, it does not appear that the revised CGMP guidance has changed this sentiment.
- The Academy appreciates FDA's efforts to craft policy that encourages outsourcing facilities to make low-volume drugs available through more flexible testing requirements.
- Unfortunately, new policy does not appear to have fixed the issue and many ophthalmic drugs remain unavailable for office-use.





Alternative Policy

- The Academy urges the FDA to allow for 503A traditional compounding pharmacies to fill low-volume orders of drugs unavailable from 503B outsourcing facilities for office-use.
- The FDA could put a quantity limit on these orders.

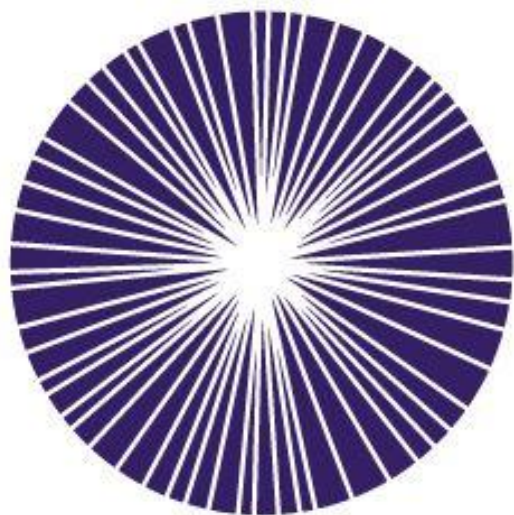




New Avastin Issue

- In response to 2018 Biologics Guidance, 503B facilities have needed to change operations to align with USP 789.
 - Only one currently available syringe type allows facilities to meet standards during testing
- This has caused issues with supply and impacted physician access to repackaged Avastin.
- AAO has been working with outsourcing facilities to address this issue in a timely manner.





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